

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE)) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)

)
THIS DOCUMENT RELATES TO:)
)
SHEILA BROWN, et al.)) CIVIL ACTION NO. 99-20593
v.)
)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM AND PRETRIAL ORDER NO.

Bartle, C.J.

August 29, 2007

Janie L. Moore ("Ms. Moore" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Mervin L. Moore, Ms. Moore's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See (continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. Part I of the Green Form is to be completed by the claimant or the claimant's representative. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, Part III is to be completed by the claimant's attorney if he or she is represented.

In July 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Gregory R. Boxberger, M.D. Based on an echocardiogram dated March 30, 2000, Dr. Boxberger attested in Part II of her Green Form that she suffered from moderate mitral regurgitation, a reduced ejection fraction in the range of 40% to 49%, and an abnormal left atrial

3(...continued)

Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period, or who took the drugs for 60 days or less, or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

dimension.⁴ Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$467,536.

In the report of claimant's echocardiogram, Dr. Boxberger stated that claimant had "[m]oderate mitral regurgitation based on RJA to LAA ratio of .20." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Boxberger also estimated claimant's ejection fraction as 45%. An ejection fraction is considered reduced for purposes of a mitral valve claim if it is measured as less than or equal to 60%. See id. § IV.B.2.c.(2) (b). Finally, Dr. Boxberger stated that claimant had a "[m]ildly dilated left atrium at 4.1 cm." The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view. See id. § IV.B.2.c.(2) (b).

In September 2003, the Trust forwarded the claim for review by Susan A. Mayer, M.D., one of its auditing

4. Dr. Boxberger also attested that claimant had endocardial fibrosis. In letters dated September 3, 2003 and September 12, 2003, however, claimant stated that Dr. Boxberger erroneously selected endocardial fibrosis on the Green Form and that this condition was not at issue in her claim.

cardiologists. In audit, Dr. Mayer concluded that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation because claimant's echocardiogram demonstrated only mild mitral regurgitation. Dr. Mayer calculated claimant's RJA/LAA ratio to be 15.9%, which is "consistent with mild mitral regurgitation." Dr. Mayer, however, found that there was a reasonable medical basis for the attesting physician's findings that claimant had an abnormal left atrial dimension and a reduced ejection fraction.⁵

Based on Dr. Mayer's finding of mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Moore's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁶ In contest, claimant submitted a supplemental report by Dr. Boxberger, in which he confirmed his

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust did not contest the attesting physician's findings of a reduced ejection fraction or an abnormal left atrial dimension, each of which is one of the conditions needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Moore's claim.

finding of moderate mitral regurgitation. Claimant also submitted expert reports by G. Whitney Reader, M.D., who stated that claimant's level of mitral regurgitation was "at least 20% RJA/LAA," Roger W. Evans, M.D., who stated that claimant's "RJA/LAA ratio is 20%," and Dan A. Francisco, M.D., who stated that claimant's "RJA/LAA ratio is approximately 20%." Claimant argued that the findings of Drs. Boxberger, Reader, Evans, and Francisco established a reasonable medical basis for her claim. Claimant also asserted that Dr. Mayer failed to apply a "reasonable medical basis" standard and, instead, substituted her own personal opinion.

The Trust then issued a final post-audit determination, again denying Ms. Moore's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7; PTO No. 2807 (Mar. 26, 2003), Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Moore's claim should be paid. On September 7, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 3901 (Sept. 7, 2004).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on November 4, 2004. Claimant submitted a sur-reply on November 23, 2004. Under the

Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁷ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned Technical Advisor, James F. Burke, M.D., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor's Report are now before the court for final determination. Id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she suffered from moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there was no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there was a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

7. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

In support of her claim, Ms. Moore argues that the issue is not whether her echocardiogram shows moderate mitral regurgitation, but whether there is a reasonable medical basis for Dr. Boxberger's finding that she had moderate mitral regurgitation. Claimant asserts that the collective findings of Drs. Boxberger, Reader, Evans, and Francisco establish a reasonable medical basis for her claim. Finally, claimant contends that inter-reader variability accounts for the difference in opinion between the auditing cardiologist and her four physicians.

In response, the Trust argues that claimant misinterprets the concept of inter-reader variability. The Trust also maintains that the standard of review is whether there is a reasonable medical basis for the attesting physician's finding and not whether one party can collect more opinions than the other. Finally, the Trust asserts that claimant's experts did not rebut the specific findings of the auditing cardiologist.⁸

The Technical Advisor, Dr. Burke, reviewed claimant's echocardiogram and concluded that there was a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. Specifically, Dr. Burke concluded that:

In the apical four chamber view, I found 16 beats with satisfactory color flow Doppler imaging. Measuring several beats with the greatest amount of mitral regurgitation, I

8. In a sur-reply, claimant reiterated her arguments concerning the reasonable medical basis standard and inter-reader variability.

found a RJA/LAA ratio of greater than 20% - in the moderate range.

In the apical two chamber view, I found 13 beats with satisfactory color flow Doppler imaging. Measuring several beats with the greatest amount of mitral regurgitation, I found a RJA/LAA ratio of greater than 20% - in the moderate range.

In the apical long axis view, I found 6 beats with satisfactory color flow Doppler imaging. Using several beats with the greatest amount of mitral regurgitation, I found a RJA/LAA ratio of greater than 20% - in the moderate range.

* * *

As I found many beats in the three apical views with mitral regurgitation over 20%, as well as many beats with mitral regurgitation under 20%, my overall impression was the patient has mild to moderate mitral regurgitation.

After reviewing the entire Show Cause Record before us, we find that claimant has established a reasonable medical basis for her claim. Claimant's attesting physician, Dr. Boxberger, reviewed claimant's echocardiogram and found that claimant had moderate mitral regurgitation.⁹ Although the Trust contested the attesting physician's conclusion, Dr. Burke confirmed the attesting physician's findings.¹⁰ Specifically, Dr. Burke concluded that "there is a reasonable medical basis for the

9. Although unnecessary for resolution of this claim, as noted above, claimant also submitted expert reports of three additional cardiologists who similarly concluded that claimant had moderate mitral regurgitation.

10. Despite an opportunity to do so, the Trust did not submit a response to the Technical Advisor Report. See Audit Rule 34.

Attesting Physician's answer to Green Form Question C.3.a. that the echocardiogram in question demonstrates moderate mitral regurgitation."

As stated above, moderate or greater mitral regurgitation is present where the RJA in any apical view is equal to or greater than 20% of the LAA. See Settlement Agreement § I.22. Here, Dr. Burke determined that "many beats in the three apical views [had] mitral regurgitation over 20%." Under these circumstances, claimant has met her burden in establishing a reasonable medical basis for her claim.

For the foregoing reasons, we conclude that claimant has met her burden in proving that there is a reasonable medical basis for her claim and consequently is entitled to Matrix Benefits. Therefore, we will reverse the Trust's denial of the claims submitted by Ms. Moore and her spouse for Matrix Benefits.

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AND NOW, on this 29th day of August, 2007, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the final post-audit determination of the AHP Settlement Trust is REVERSED and that claimants, Janie L. Moore, and her spouse, Mervin L. Moore, are entitled to Matrix A-1, Level II benefits. The Trust shall pay such benefits in accordance with the Settlement Agreement and Pretrial Order No. 2805 and shall reimburse claimant for any Technical Advisor costs incurred in the Show Cause process.

BY THE COURT:

/s/ Harvey Bartle III

C.J.